Attorney Docket No. 0150.00

CLAIMS

Please amend the claims as shown.

As amended, the following listing of claims will replace all prior versions and listings of claims in the application:

1. (Previously Presented) An aerosolization apparatus comprising:

a container containing a pharmaceutical formulation, the pharmaceutical formulation comprising an active agent, the container further containing a first pressurizer comprising a fluid propellant;

a metering chamber in communication with the container, the metering chamber adapted to hold a metered amount of the pharmaceutical formulation;

a valve to allow the metered amount of the pharmaceutical formulation to be released from the metering chamber when the valve is actuated; and

a second pressurizer that applies pressure to the pharmaceutical formulation in the metering chamber while the pharmaceutical formulation is being released from the metering chamber,

wherein the first and second pressurizers independently supply pressure to the pharmaceutical formulation, and

wherein the metering chamber is sized so that at least 2 mg of the active agent is aerosolized for delivery to a user during inhalation.

2. (Previously Presented) An aerosolization apparatus according to claim 1 wherein the second pressurizer changes the volume of the metering chamber.

3. (Previously Presented) An aerosolization apparatus according to claim 1 wherein the second pressurizer decreases the volume of the metering chamber.

4. (Previously Presented) An aerosolization apparatus according to claim 1 wherein the second pressurizer changes the volume of the metering chamber and wherein the aerosolization apparatus further comprises a mechanism for returning the metering chamber to its original volume following actuation.

5. (Original) An aerosolization apparatus according to claim 1 wherein the metering chamber is sized so that at least 3 mg of the active agent is be aerosolized for delivery to a user during inhalation.

6. (Original) An aerosolization apparatus according to claim 1 wherein the metering chamber is sized so that at least 5 mg of the active agent is be aerosolized for delivery to a user during inhalation.

7. (Original) An aerosolization apparatus according to claim 1 wherein the metering chamber is adapted to contain a volume of the pharmaceutical formulation of at least 50 µl prior to actuation of the valve.

8. (Original) An aerosolization apparatus according to claim 1 wherein the metering chamber is adapted to contain a volume of the pharmaceutical formulation of at least 150 µl prior to actuation of the valve.

9. (Original) An aerosolization apparatus according to claim 1 wherein the metering chamber is adapted to contain a volume of the pharmaceutical formulation of at least 300 µl prior to actuation of the valve.

10. (Previously Presented) An aerosolization apparatus according to claim 1 wherein the pharmaceutical formulation comprises a powder, and a particle size distribution of aerosol particles generated is at least about 50% having a diametric size of from 0.1 µm to 10 µm.

11. (Previously Presented) An aerosolization apparatus according to claim 10 wherein at least 80% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm.

12. (Previously Presented) An aerosolization apparatus according to claim 1 wherein the second pressurizer comprises a plunger that is capable of changing the volume of the metering chamber.

13. (Previously Presented) An aerosolization apparatus according to claim 1 wherein the second pressurizer comprises a plunger that is capable of changing the volume of the metering chamber, wherein the plunger is adapted to be pressurized by the pressure of the pharmaceutical formulation within the container.

14 - 15 (Cancelled)

16. (Previously Presented) An aerosolization apparatus according to claim 1 wherein the second pressurizer comprises a source of pressurized gas.

17. (Previously Presented) An aerosolization apparatus according to claim 1 wherein the second pressurizer comprises a source of pressurized gas, wherein the source of pressurized gas is within the container.

18 – 28 (Cancelled)

29. (Previously Presented) An aerosolization apparatus comprising:

a container containing a pharmaceutical formulation, the pharmaceutical formulation comprising insulin, the container further containing a first pressurizer comprising a fluid a propellant;

a metering chamber in communication with the container, the metering chamber adapted to hold a metered amount of the pharmaceutical formulation;

a valve to allow the metered amount of the pharmaceutical formulation to be released from the container when the valve is actuated; and

a second pressurizer that applies pressure to the pharmaceutical formulation in the metering chamber while the pharmaceutical formulation is released from the metering chamber, wherein the first and second pressurizers independently supply pressure to the pharmaceutical formulation.

30. (Previously Presented) An aerosolization apparatus according to claim 29 wherein the second pressurizer comprises a plunger that is capable of changing the volume of the metering chamber, wherein the plunger is adapted to be pressurized by the pressure of the pharmaceutical formulation within the container.

31. (Cancelled)

32. (Previously Presented) A method of aerosolizing a pharmaceutical formulation, the method comprising:

containing a pharmaceutical formulation in a container, the pharmaceutical formulation comprising an active agent and a propellant, the propellant comprising a first pressurizer;

metering an amount of the pharmaceutical formulation into a metering chamber in communication with the container;

releasing the pharmaceutical formulation from the metering chamber; and

applying pressure within the metering chamber with a second pressurizer during the release of the pharmaceutical formulation, wherein the first and second pressurizers independently supply pressure to the pharmaceutical formulation, and

wherein at least 2 mg of the active agent is be aerosolized for delivery to a user during inhalation.

33. (Previously Presented) A method according to claim 32 wherein the pressure is applied to the metering chamber by decreasing the volume of the metering chamber.

34. (Original) A method according to claim 32 wherein at least 3 mg of the active agent is aerosolized for delivery to a user during inhalation.

35. (Original) A method according to claim 32 wherein at least 5 mg of the active agent is aerosolized for delivery to a user during inhalation.

36. (Previously Presented) A method according to claim 32 wherein the pharmaceutical formulation comprises a powder, and a particle size distribution of aerosol particles generated is at least about 50% having a diametric size of from 0.1 μm to 10 μm.

37. (Previously Presented) A method according to claim 36 wherein at least 80% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm.

38. (Original) A method according to claim 32 wherein the pressure is applied by a plunger.

39. (Original) A method according to claim 32 wherein the pressure is applied by a plunger, wherein the plunger is adapted to be pressurized by the pressure of the pharmaceutical formulation within the container.

40. (Cancelled).

41. (Original) A method according to claim 32 wherein the pressure is applied from a source of pressurized gas.

42. (Cancelled)

43. (Previously Presented) A method of aerosolizing an insulin formulation, the method comprising:

containing a pharmaceutical formulation in a container, the pharmaceutical formulation comprising insulin and a propellant, the propellant comprising a first pressurizing means;

metering an amount of the pharmaceutical formulation in a metering chamber in communication with the container;

releasing the pharmaceutical formulation from the metering chamber; and

applying pressure, with a second pressurizing means, within the metering chamber during the release of the pharmaceutical formulation, wherein the first and second pressurizing means independently supply pressure to the pharmaceutical formulation.

44. (Original) A method according to claim 43 wherein at least 2 mg of insulin is aerosolized for delivery to a user.

45. (Original) A method according to claim 43 wherein at least 3 mg of insulin is aerosolized for delivery to a user.

46. (Original) A method according to claim 43 wherein at least 5 mg of insulin is aerosolized for delivery to a user.

47. (Original) A method according to claim 43 wherein the pressure is applied by a plunger, wherein the plunger is adapted to be pressurized by the pressure of the pharmaceutical formulation within the container.

48. (Cancelled)

49. (Original) A method according to claim 43 wherein the pressure is applied from a source of pressurized gas.

50. (Cancelled)